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EXAMINER	
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ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,994	BAUMANN ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-21 and 27-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted November 26, 2007 wherein claims 11, 13, 20, 21, 27, and 34 are amended and new claims 35-38 are introduced. This application was filed July 28, 2003 and makes no priority claims.

Claims 1-38 are pending in this application.

Claims 11-21 and 27-38 as amended are examined on the merits herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 26, 2887 has been entered.

Applicant's declaration under 37 CFR 1.131 by Leslie S. Baumann has been fully considered and entered into the record. The declaration is discussed below as it relates to the rejections of record in the previous office action.

Applicant's amendment, submitted November 26, 2007, with respect to the rejection of instant claims 20, 21, 27, and 28 under 35 USC 102(b) as being anticipated

by Stockfleth et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require the presence of fine lines and clinical wrinkles, which are not disclosed by Stockfleth et al. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 26, 2007, with respect to the rejection of instant claim 29 under 35 USC 103(a) as being obvious over Stockfleth et al., has been fully considered and found to be persuasive to remove the rejection as claim 29 has been amended to require the presence of fine lines and clinical wrinkles, which are not disclosed by Stockfleth et al. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 26, 2007, with respect to the rejection of instant claims 2 and 21 under 35 USC 103(a) as being obvious over Maibach et al., has been fully considered and found to be persuasive to remove the rejection as claim 29 has been amended to require the presence of fine lines and clinical wrinkles, which are not disclosed by Maibach et al. Therefore the rejection is withdrawn.

The following grounds of rejection of record in the previous office action are maintained, as applied to the currently amended claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the specification fails to enable one skilled in the art to treat the recited disorders using **the specific compounds recited in claims 33 and 34**.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a method comprising administering a dermatological composition to a subject having fine lines and/or wrinkles.

The state of the prior art: Imiquimod, a toll-like receptor agonist and interferon inducer, is known to be useful as a dermatological agent for treating a variety of conditions such as precancerous lesions and viral infection. Miller et al. (US patent publication 2004/0180919, application 10/799999, of record in previous action) additionally discloses that imiquimod is useful for treating fine lines and wrinkles.

The specific compounds disclosed in instant claims 33 and 34 share the core imizadoquinolone structure with imiquimod, but they differ in that the compounds of claim 33 possess a piperidyl-alkyl-substituent at the 1-N position, while those of claim 34 leave this nitrogen entirely unsubstituted. These compounds are never disclosed to possess toll-like receptor activity, interferon induction, or any cytotoxic, antiviral, or antitumor activity. Rather, the compounds of claim 33 are disclosed by Izumi et al. (of record in previous action) to not be IFN inducers and in fact to suppress TNF-α, (abstract, p. 2544, left column, first paragraph, p. 2545, left column, first paragraph) and the compounds of claim 34 are disclosed by van Galen et al. (of record in previous action) to be adenosine receptor agonists, with no mention of toll-like receptor activation or interferon induction. Based on these references, it is seen to be unlikely that these compounds will act on the same target, work by the same mechanism, or produce the same effect as imiquimod or any of the other claimed toll-like receptors. Therefore the prior art does not provide any reason to expect that these compounds possess the claimed activity.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: According to Silverman (Reference of record in previous action) Agonists against a particular receptor exhibit

close structural similarity, while there are a wider range of structures that act as antagonists. (p. 69, first paragraph) It is easier to design an antagonist than an agonist. (p. 70, first paragraph) Silverman also discloses that most xenobiotic compounds that interact with receptors are antagonists. (p. 70, third paragraph) Thus the design and/or identification of new agonists at a particular receptor is highly unpredictable, and a randomly chosen derivative of a particular agonist is likely to be an antagonist..

The Breadth of the claims: The claimed invention includes a method for treating certain dermatological conditions by administering a certain class of compounds.

The amount of direction or guidance presented: Applicant's disclosure does not contain any information about the biological properties, molecular targets, or therapeutic utility of these compounds aside from the statement on p. 11 that derivatives of imiquimod described in the Izumi et al. and van Galen et al. references can be used in the claimed invention. No evidence is provided that these compounds are actually toll-like receptor activators or interferon inducers.

The presence or absence of working examples: The only working examples provided concern the dermatological use of imiquimod, rather than any of the compounds of claims 33 and 34.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the identification of novel receptor agonists. See MPEP 2164.

The quantity of experimentation necessary: In order to make and use the invention of claims 33 and 34, one skilled in the art would have to determine the biological activity and mode of action of the claimed compounds. Applicant has provided no evidence that these compounds are toll-like receptor agonists, or that they are capable of producing the same biological effects as imiquimod. The only evidence provided is their alleged structural similarity to imiquimod. As discussed earlier, it is much easier to antagonize than to activate a receptor, and many compound that bear some structural similarity to known agonists are actually antagonists.

In the absence of any actual evidence that the compounds of claims 33 and 34 are useful in the claimed methods, one skilled in the art would have to perform all of the experimentation involved in determining the activity of these compounds and developing a method of using them to treat wrinkles and fine lines. Undertaking this process of experimentation, with no assistance from the prior art or Applicant's disclosure, and no expectation of success, constitutes an undue and unpredictable experimental burden in order to practice the claimed invention.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the state of the art and the lack of guidance and working examples, Applicants fail to provide information sufficient to practice the claimed invention.

Response to Arguments: Applicant's arguments, submitted November 26, 2007, with respect to the above ground of rejection, has been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claimed generic structures are not unduly broad in that they encompass a limited number of possible embodiments. However, breadth is only one of the factors to be considered and a narrow scope does not render an invention enabled if there is no reason to think that any member of the claimed genus is functional, as is the case for these claims.

Applicant further argues that the rejected claims do not require that the claimed compounds work by toll-like receptor activation, interferon induction, or antiviral or antitumor activity, But merely that they treat fine lines and clinical wrinkles, and that scientific theory is not a requirement for patentability. However, lack of a scientific theory weighs against enablement in the absence of other factors favoring patentability. In particular, there must be some reason to believe that the invention actually works. Typically this evidence comes from scientific theory and/or experimental evidence. Evidence that a particular embodiment is enabled, such as a disclosed working example, does not automatically enable each and every embodiment that Applicant happens to recite. Rather, the working examples must be evaluated based on the knowledge available to one skilled in the art. If the knowledge available in the art would suggest that the claimed compound has a different function than the working examples,

for example because it is an antagonist of a particular receptor rather than an agonist, then it is not considered to be enabled for the same function as the disclosed examples. One cannot arbitrarily pull compounds at out of the prior art based on a subjective structural similarity and claim that they possess the same utility as the disclosed examples. To claim a particular utility for a prior art compound that has not been tested for the claimed use, there must be some theoretical reason to believe that the compound will possess the same biological or pharmaceutical properties as the claimed invention, for example by being an agonist at the same receptor. In the instant case, the silence of the prior art as to the claimed invention's utility, and the explicit negative statements by Izumi et al. as to the compound being an "imiquimod analog without IFN-α inducing activity," coupled with the teaching in the art exemplified by Silverman that derivatives and analogs of agonists are often antagonists to the same receptor, combined with the utter lack of any instance anywhere in the prior art, the disclosure, or the post-filing date art of these compounds being used to treat fine lines or clinical wrinkles, would lead one skilled in the art to believe that the compounds of claims 33 and 34 are nonfunctional.

Finally, Applicant argues that according to MPEP 2164.04, issues of enablement should not be raised for the first time in a final office action. What is actually said in MPEP 2164.04 is that according to the principles of compact prosecution, "if an enablement rejection is appropriate, the first Office action on the merits should present the best case with all the relevant reasons, issues, and evidence so that all such rejections can be withdrawn if applicant provides appropriate convincing arguments

and/or evidence in rebuttal." The above rejection could not be made in the first action on the merits because the rejected claims were only introduced in an amendment after said office action. Note that the new claims included species not covered by any of the original claims examined in the first action on the merits. It is equally inconsistent with the principles of compact prosecution to issue multiple non-final office actions in response to new rejections necessitated by subsequent amendments.

For these reasons the rejection is deemed proper and maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-17, 19-21, and 31, and claims 27-29 as recently amended are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (US patent publication 2004/0180919, application 10/799999, of record in previous action) Miller et al. discloses a method of improving skin quality by topical administration of an immune response modifier. (p. 1, paragraphs 0004-0005 and 0015) In particular, improving skin quality involves treating fine lines and wrinkles. (p. 1, paragraphs 0001 and 0007, p. 4, paragraph 42) Suitable immune response modifiers include imidazoquinoline amines,

(p. 2, paragraph 0024) in particular 1-(2-methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine, otherwise known as imiquimod. (p. 3, paragraph 0025) The active agent is administered in a formulation having any one of various concentrations including about 1% or 5%. (p. 4, paragraph 0038) The composition is administered 2, 3, 5, or 7 times a week. (p. 4, paragraphs 0047 and 0048, p. 5, paragraph 0060 and table 1) In one specific example, 5% imiquimod is administered daily to treat wrinkles, and the subjects are evaluated by visual and photographic assessment. (p. 6, paragraphs 0067-0074) The various embodiments disclosed in this reference are the same as the method of treating clinical wrinkles recited in the instant claims. Furthermore they are reasonably considered to be a method of inducing an immune cytotoxic response in a section of damaged dermal or epidermal tissue, because they comprise administering the same compound to the same subjects as instant claims 20 and 21. Although Miller et al. does not explicitly state that the applied composition attracts macrophage cells to the area, activates the toll-like receptor 7, or identifies a precancerous region of skin, all of these elements are inherent in the method as disclosed by Miller et al. Furthermore, it is an inherent property of a method of applying imiquimod to an area of skin exhibiting fine lines and clinical wrinkles that any precancerous regions in the treated area would become inflamed and thus be identified. Note that the claim limitation "identifying a precancerous region of skin," does not require that the skin to which the imiquimod is applied actually be precancerous, as the status (precancerous or non-precancerous) is not known until after the active agent has been applied and the skin has or has not become inflamed. The mechanism by which the claimed method works is not given

patentable weight over the prior art. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein. Thus Miller et al. anticipates the claimed invention.

Response to Arguments: Applicant's arguments, submitted November 26, 2007, with respect to the above ground of rejection, has been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claimed invention was constructively reduced to practice before the effective filing date of Miller et al. on March 13, 2003. A declaration under 37 CFR 1.131 by Leslie S. Baumann has been submitted in which it is stated that the invention was submitted in a confidential disclosure on June 20, 2002 and practiced clinically during the summer and fall of 2002. However, according to 37 CFR 1.131(b), when a declaration is made under 37 CFR 1.131 to antedate a reference cited under 35 USC 102 or 103,

"(b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application.

Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained."

The declarant explains that appropriate notes and medical records are not attached because patient medical information is protected under federal law and university policy. However, in such cases it is appropriate to include copies of the relevant records with all identifying information such as names blacked out to preserve the patients' privacy.

Furthermore, MPEP 715 states that a declaration under 37 CFR 1.131 is not appropriate "Where the reference U.S. patent or U.S. patent application publication claims the same patentable invention." Applicant notes that imiquimod itself is never recited in the claims published with Miller et al. However, when considering whether two applications claim the same invention, the specifications must be taken into account in order to interpret the categories used in the claims. In the instant case, p. 3, paragraph 0025 recites various embodiments of the term "imidazoquinolone amine," including 1-(2-methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine, the species of the instant claims. Therefore one of ordinary skill in the art would interpret the claims of Miller et al. as including imiquimod as a specific embodiment, thereby claiming the same invention as the instant application.

For these reasons the rejection is deemed proper and maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 18 and new claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US patent publication 2004/0180919, application 10/799999, of record in previous action) The disclosure of Miller et al is discussed above. Miller et al. does not specifically disclose a method comprising administration of imiquimod in a composition comprising 1.25% imiquimod. Miller et al. also does not disclose a method in which the imiquimod is applied two, three, or four times daily.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the invention of Miller et al. administering the imiquimod in a concentration of 1.25%. One of ordinary skill in the art would have been motivated to modify the invention in this way because Miller et al. already discloses various concentrations encompassing 1.25%, including about 1%. One of ordinary skill in the art would reasonably have expected success because adjusting the dosage level of a known compound is well within the ordinary level of skill in the art.

It would also have been obvious to one of ordinary skill in the art to apply the imiquimod in divided doses of tow, three, or for times daily. One of ordinary skill in the art would have recognized that a therapeutic agent can be applied in divided doses more than once per day. One of ordinary skill in the art would reasonably have

expected success because minor adjustments to a dosing regimen such as using divided doses, are well within the ordinary and routine level of skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Arguments: Applicant's arguments, submitted November 26, 2007, with respect to the above ground of rejection, has been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments with respect to this rejection are the same as those submitted with respect to the rejection under 35 USC 102(e) over Miller et al. above, and are not found persuasive for the same reasons. Therefore the rejection is maintained.

Claims 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US patent publication 2004/0180919, application 10/799999, of record in previous action) in view of Gerster (US patent 4689338, of record in previous action) The disclosure of Miller et al is discussed above. Miller et al. does not specifically disclose a method comprising administering one of the imiquimod derivatives disclosed in instant claims 30 and 32.

Gerster discloses a class of compounds including various compounds of instant claims 30 and 32. (column 2, line 1 – column 3, line 25, R_1 = benzyl, phenylethyl, or phenyl, substituted with 1-2 C_{1-4} alkyl groups, R_2 = H, n = 0) These compounds exhibit antiviral activity, (column 6, lines 45-68) and are immunomodulators and interferon inducers. (column 8, lines 12-20), also table XIII in column 33)

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the invention if Miller et al. with the aforementioned compounds of Gerster. One of ordinary skill in the art at the time of the invention would have been motivated to use these compounds because these compounds are disclosed to be immunomodulators and interferon inducers, and thus reasonably considered to be immune response modifiers according to Miller et al. Also, the compounds are structurally similar to imiquimod and other imiadazoquinolines disclosed by Miller et al. One of ordinary skill in the art would have reasonably expected success because substituting one active agent with another having the same activity is within the ordinary and routine level of skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Arguments: Applicant's arguments, submitted November 26, 2007, with respect to the above ground of rejection, has been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments with respect to this rejection are the same as those submitted with respect to the rejection under 35 USC 102(e) over Miller et al. above, and are not found persuasive for the same reasons. Therefore the rejection is maintained.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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